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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,535	07/05/2005	David Michael Evans	040283-0242	1213
22428 7590 01/15/2009 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 01/15/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/506,535

**Applicant(s)**

EVANS, DAVID MICHAEL

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants dated Oct. 15, 2008 have been entered and considered carefully.

Claims 1-8, 12 are continuously prosecuted. Claims 9-11 stayed withdrawn from consideration.



Applicants argued that the Griesbacher et al. reference is not proper 102(f) since the instant application has an earlier filing date. Please note that the instant oath has clearly verified that the 371 date of the instant application is the PCT filing date 3/4/2003 and the amendments were made in Sept. 3, 2004 to the claims as entered into the national stage. There is no claim to foreign priority in the beginning of the specification. Therefore, at most the filing date of this 371 case is Mar. 4, 2003 for which the Greisbacher et al was *received* on Mar. 12, 2002 and published in Sept. 2002 is very much prior to the instant case.

Especially, with respect to the restrictable claims 9-11. It is noted that, the "utility" of the FE999024 was *different* from the elected example 3. Please note, on page 2 of the specification it was stated that the problem to be resolve by the instant application is "...there remains a need for compounds that selective inhibit plasma kallikrein and not tissue kallikrein". On p. 27-28, example 59, it was disclosed in vitro testing of the "inhibition constant for *plasma kallikrein*. Therefore, the elected example 3 which is selective plasma kallidrein compound is the concept of the instant application and the other non-plasma selective compounds are the inoperable compounds for the instant application. Therefore, different compounds, different utility (p.28-29, compound 3 is plasma kallikrein selective, compound 40 is tissue kallidrein selective) are improper Markush grouping and restrictable especially an anticipatory compound was disclsoed by a different inventive entity.

2. The rejection of claims 1-8, 12 under 35 USC 102(f) is maintained for reason of record.

Please note that the same explanation with respect to filing date supra is also applicable here and incorporated by reference. The issue is the same as In re Katz 215 USPQ 14 and the same requirement according to MPEP §2137 is applicable here.

3. The rejection of claim 1 under 35 USC 112 second paragraph is maintained for reason of record.

Applicants' explanation that the o-xylene is  cannot resolve the indefiniteness of the scope. Please note that o-xylene can be  and the ring structure with the remaining molecule would be very different. It is required that applicants find the proper antecedent basis in the specification supporting the proper structure and incorporate the appropriate structural formulation instead of the ambiguous term o-xylene.

The rejection of claim 8 under 112 second paragraph is moot in view of the amendment.

4. The rejection of claims 8 and 12 under 112 first paragraph is maintained for reason of record.

Applicants argued that since claim 8 has incorporated the term "therapeutically effective amount" the issue of enablement is resolved. This is not the situation, especially in claim 12, the therapeutically effective amount was provided to be for treatment of "*disease condition selected from the group consisting of inflammatory bowel disease, arthritis, inflammation, septic shock, hypotension, cancer, adult respiratory distress syndrome, disseminated intravascular coagulation, cardiopulmonary bypass surgery and bleeding from post-operative surgery*". Please note that an effective amount for treating cardiopulmonary bypass surgery, ordinarily is an anti-thrombotic amount, would kill the person wherein stopping bleeding is needed. In addition, inhibitor of plasma kallikrein is antithrombotic (see Colman) which has not been correlated to inflammation, cancer, or stop bleeding etc.

5. The rejection of claims 1-8 and 12 under 35 USC 103(a) over McIver in view of Garrett and Peak is maintained for claims 1, 2, 5, 6, 8 and 12 when R2 is broadly arylalkyl.

The scope wherein R2 is limited to claims 3, 4 or 7 differ from the prior art with the addition structure feature that naphthylalkyl was demarcated in the claims.

6. The scope of claims 3, 4 and 7 would be allowable upon clarification of the inventorship issue.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang  
Jan. 12, 2009*

*/Celia Chang/  
Primary Examiner  
Art Unit 1625*